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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,852	02/19/2002	Jeremy Marshall	3003-1004	2432
466	7590	01/11/2005	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

**Office Action Summary**

Application No.

10/049,852

Applicant(s)

MARSHALL ET AL.

Examiner

Sarah K Webb

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/18/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 8, 9, 18 and 21 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 6, 7, 10-17, 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,895,147 to Bodicky et al. In view of US Patent No. 5,569,189 to Parsons.

Bodicky discloses a lancet that includes:

- barrel 12;
- means 30 for carrying a lancet 70;
- hammer 16;
- barrier 20 to the rear of the hammer;
- spring 34 acting between the hammer and barrier;
- trigger 48.

The nose section (24) of the device is removable to allow insertion of the lancet (70) (column 5, lines 26-28). Bodicky fails to form the barrier to be user-adjustable so that rotation of the barrier changes the degree of compression of the spring. Bodicky does teach that the penetration of the lancet should be adjustable for different patients (column 2, lines 40-45). Parsons discloses an injection device that is analogous to Bodicky. Since both devices are adapted toward injecting material into the skin of a patient, they are of analogous art. The two devices also share many of the same structural characteristics, as Parsons also includes:

- barrel 30;
- hammer 204;
- barrier 42 to the rear of the hammer;
- spring 34 acting between the hammer and barrier;
- trigger 58.

Parsons teaches that the barrier can be configured as a means for adjusting the degree of compression of the spring. Column 9, lines 10-15 state that the barrier can be screw that is used to "selectively shorten or lengthen the channel." The barrier is adjusted by rotation, which

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is inherently performed by the user. Lines 21-28 of column 9 further describe the barrier. The corresponding threads of the barrier and barrel are considered to meet the limitations of claim 2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the barrier of Bodicky to be adjustable by rotation, as Parsons teaches that this allows the user to change the compression of the spring. This allows the penetration of the lancet to be adjusted for varying needs of different patients.

2. Claims 5, 9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky in view of Parsons, as applied to claim 2 above, and further in view of US Patent No. 5,871,494 to Simons et al.

Claim 5:

The modified Bodicky device fails to include a sleeve spring at the rear of the barrel. As explained further in the prior office action, Simons discloses another lancet device with a cocking mechanism. Simons teaches that the cocking mechanism can be in the form of a sleeve (562) on the rear portion that is spring (568) urged forwardly. The sleeve (562) retracts the hammer (546) when pulled back and disconnects from the hammer when released and moved forward (column 12, lines 16-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sleeve spring at the rear portion of the barrel of the modified Bodicky device, as Simons teaches that this structure provides cocking mechanism for the drive spring.

Claim 9:

Bodicky fails to use a lancet carrying means that spring urges the lancet tip rearwardly. Simons forms the lancet carrying means as a tubular member that is spring (228) urged

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rearwardly, wherein the lancet (216) fits into the forward end of the carrying means (Figure 3C-D). Simons teaches that this structure exposes the lancet only when actuated, so that the user is protected against accidental pricks and scratches (column 9, lines 17-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a lancet carrier in the modified Bodicky device that normally biases the lancet rearwardly, as Simons teaches that this prevents the user from being accidentally pricked or scratched by the lancet tip.

### ***Response to Arguments***

3. Applicant's arguments, see pages 9 and 10, filed 10/18/04, with respect to the rejection(s) of claim(s) 1,2,5,8,9, and 18 under Simons have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bodicky and Parsons.

4. Applicant's arguments with respect to Simons and Parsons being nonanalogous have been fully considered but they are not persuasive. Simons and Bodicky are devices that inject the skin, and Parsons is also a device that injects the skin. Since all the devices are adapted toward injecting material into the skin of a patient, they are of analogous art. The devices also share many of the same structural characteristics, as explained in more detail above.

5. Applicant argues that the barrier of Parsons is not available for user adjustment. Parsons does point out that the rear barrier, or screw, is adapted to be adjusted by a user. Column 9, lines 10-15 state that the barrier can be screw that is used to "selectively shorten or lengthen the channel."

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***Allowable Subject Matter***

6. Claims 3,4,6,7,10-17, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1/7/05

SKW

*Julian W. Woo*

JULIAN W. WOO  
PRIMARY EXAMINER